



AdvaMed

Advanced Medical Technology Association

AdvaMed Response to Request for Public Comments on Implementation of the CHIPS Incentives Program

Docket Number: 21006-0213

November 14, 2022

AdvaMed would like to thank the National Institute of Standards and Technology (NIST) and the CHIPS Office for the opportunity to provide the perspective of the U.S. medical devices industry on the CHIPS Incentives Program following the enactment of the CHIPS Act 2022. These comments build upon our prior submission in March of this year.

About AdvaMed – Our Industry’s Workers and Technologies

AdvaMed is the world’s largest medical technology association, with over 400 members ranging from the largest to the smallest medical technology innovators and companies. Our industry directly employs 397,000 people, at an average annual salary of \$88,096—49% higher than the average across all industries and 18% higher than the corresponding premium of all manufacturing jobs. Every 5 medtech industry jobs creates an additional 7 jobs. Of the nearly 15,000 medtech establishments, 94% are small businesses that employ fewer than 100 people.

MedTech Industry and Semiconductor Chips

Despite being less than 1% of the overall semiconductor chip market, manufacturers of medical devices and diagnostics rely on semiconductor chips for a vast array of technologies. These include but are not limited to capital equipment such as imaging systems, diagnostic assay systems, instrument sterilization equipment, and robotic surgical systems, patient monitoring systems (glucose, oxygen levels, blood pressure, etc.), cardiovascular care such as EKG, pacemakers and defibrillators, respiratory care such as ventilators and CPAP, orthopedic implants and a broad spectrum of technology enabled systems and applications in the healthcare delivery system. It is also worth noting that there is a vast ecosystem of technologies including automation and molding that directly support the manufacture of medical technologies. This equipment also relies on semiconductor chips.

Over the past year and a half, the chips shortage has become an acute industry-wide issue for the hundreds of diagnostics, therapeutics, and capital equipment companies that produce essential medical technologies that support patient health. As the semiconductor supply chain challenges continue, shortages stemming from allocations and decommits by chips manufactures, suppliers and brokers have disrupted medical technology manufacturing and the delivery of patient care. In the short term, AdvaMed is calling for the federal government and chips supply chain partners to prioritize the delivery of patient care by ensuring that medical device manufactures receive the comparatively small number of chips, many of which are older generation, they need to continue operations. Failure to do so could result in further production disruptions and the inability to repair the existing healthcare infrastructure, directly impacting the ability to provide patient care. Overtime, pervasive shortages could also begin to drive up healthcare prices and restrict innovation as companies are forced to pay even higher prices for scarce chips or redesign and



AdvaMed

Advanced Medical Technology Association

recertify technologies to accommodate their limited inventory of chips. Of note, efforts to redesign and recertify technologies, likely including review by FDA, would occur whether changing to an alternate supplier of the same generation of chip or to a newer generation of chip than what is already in a given medical device.

Recommendations

As the CHIPS Office and NIST contemplate mechanisms to design and implement the Chips Incentives program, we recommend that the agencies coordinate with critical sectors including medtech to ensure that investments are directed towards mature nodes and technologies that power medical devices that save lives.

The Department of Defense (DoD), in partnership with the Department of Commerce and private sector entities are working with 4 critical sectors – defense, transport, communications and medical devices to undertake an assessment of the chip needs of these critical industries that support our national security. Preliminary findings from this group demonstrate clearly that these critical sectors are highly reliant on mature chips sourced primarily outside the U.S. We strongly urge NIST and the CHIPS Office to coordinate with DoD on this work to ensure their findings inform future investment programs that meet our national interest. Specifically, it is essential that the CHIPS Act direct appropriated funds to chip manufacturers to support a secure, adequate, and continuous supply of mature semiconductors, especially as new federally incentivized domestic semiconductor facilities are constructed. In addition, workforce development and educational programming should also be a large factor in the incentive program to ensure the availability of skilled workforce to support the semiconductor industry growth.

As NIST and the CHIPS office undertake these programs, it is critical that they coordinate with key allies and trading partners to avoid duplication of efforts. Leading trading partners such the EU have their own chips investment programs and are looking to address the same issues as the US. Recognizing that it is not feasible to reshore the entire semiconductor supply chain, we should be working with like-minded partners and allies to coordinate the chip needs across critical sectors and invest in a way that is complimentary to ongoing efforts in other markets.

Finally, AdvaMed recommends that Commerce establish a program or interagency workstream in partnership with key agencies including FDA (i.e., FDA's Resilient Supply Chain and Shortage Prevention Program) and HHS/ASPR that evaluates the incentive program design as it relates to the evolving requirements of the U.S. healthcare system. This program could provide input into the overall process from the perspective of addressing our nation's public health and the well-being of patients. As a key part of this effort and for the reasons outlined above, we also strongly recommend a formal mechanism for regular industry consultations to ensure the incentive program proposed is directly impactful and meaningful to businesses. It is critical the U.S. government receives timely information on the semiconductor needs of the medical device industry and can act appropriately to stave off future, unnecessary shortages that could impact patient care.

#####